UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants, and Eli Lilly and Company, Intervenor-Defendant.	Case No. 4:24-cv-00953-P

Brief in Opposition to Plaintiffs' Motion for Summary Judgment

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INTRODUCTION

Plaintiffs' motion for summary judgment is essentially a rerun of their failed bid for preliminary relief. This Court has already held that Plaintiffs' claims were not likely to succeed on the merits, and Plaintiffs provide no valid reason for the Court to reach a different result now. Plaintiffs' old arguments still fail and the few new ones are unconvincing.

Plaintiffs again accuse FDA of misreading the governing provisions in the Federal Food, Drug, and Cosmetic Act (FDCA), but it is they who attempt to import non-existent methodological requirements into the statute. The FDCA does not require the agency to specify upfront the relevant time period for analysis. Nor does the statute require FDA to analyze *only* the most recent information; indeed, depending on the circumstances of the shortage in question, FDA may consider other types of information relevant to its shortage analysis. Contrary to Plaintiffs' arguments, FDA applied the plain meaning of the statute by analyzing whether there was a national (as opposed to a regional) shortage. And since compounding would be curtailed after the shortage, FDA appropriately considered whether Lilly could accommodate increased demand from patients switching from a compounded drug to Lilly's product.

Plaintiffs' attempts to undermine the validity of Lilly's supply data—and cast FDA's decision as arbitrary and capricious—are similarly unconvincing. Plaintiffs dispute Lilly's ability to supply [redacted] per month based on past production numbers, but they neglect the differences between a manufacturer's current capability and its past production. Plaintiffs' theory of a purported [redacted] is based on an apples-to-oranges comparison that proves no "shortage." Otherwise, they repeat the failed argument that FDA should have credited third-party anecdotal information, such as screenshots of wholesaler websites, online surveys, and news reports, which FDA reasonably concluded had limited probative value. The agency reasonably determined that the shortage was resolved.

Finally, from the procedural standpoint, FDA's drug shortage determination was an informal adjudication. As the Court explained in its order denying Plaintiffs' motion for emergency relief, FDA's declaratory order bore the hallmarks of an adjudication, applying a preexisting statutory

standard to a specific set of facts. Moreover, proceeding by declaratory order, rather than rulemaking, makes sense in this statutory setting. Congress directed FDA to keep the drug shortage list "up-to-date" and to protect the confidentiality of the factual material most critical to its decision. Those goals are near impossible to achieve in a rulemaking. FDA's declaratory order also does not transform into a legislative rule merely because it affects a large number of third parties. As the Court pointed out, an adjudication may affect third parties, too. FDA thus did not abuse its discretion when it proceeded by declaratory order.

Plaintiffs' motion for summary judgment should be denied on all counts.

ARGUMENT

I. FDA applied the correct legal standard and adequately explained its decision (Counts Two and Five)

In Count Two, Plaintiffs argue that FDA failed to adequately explain its decision because it did not "select a period of time for analysis, explain why it selected that period of time, of [sic] make findings of supply and demand levels for that period of time." ECF No. 122 (OFA Mot.) 9. Instead, they claim FDA improperly "[o]utsourced" those decisions to Lilly. *Id.* In Count Five, Plaintiffs claim that FDA incorrectly interpreted the governing statute. OFA Mot. 15–17. Plaintiffs are incorrect.

Period of time. Plaintiffs again insist that FDA did not identify a specific "period of time" for analysis. OFA Mot. 9. As the Court previously found, "this argument . . . plainly fails." ECF No. 100 (PI Order) 18. The statute does not contain Plaintiffs' proposed methodological requirement. And, contrary to Plaintiffs' assertion, FDA *did* specify the relevant time period.

Because the statute does not actually require FDA to specify the "period of time" for analysis, Plaintiffs instead point to the statutory definition of a "drug shortage." OFA Mot. 9 (quoting FDA App. 3,[1] in turn quoting 21 U.S.C. § 356c(h)(2)). But this language—"a period of

[1] Citations to "App." are to the Appendix in Support of Plaintiffs' Motion, ECF Nos. 122-1 through 122-9. Citations to "FDA App." are to the Appendix in Support of Federal Defendants' Motion, ECF No. 126-1. Citations to "FDA Opp. App." are to the appendix to this brief.

time when the demand or projected demand for the drug within the United States exceeds the supply of the drug"—merely identifies what a shortage is and refers to how it occurs over a "period of time." It says nothing about how FDA should *determine* whether a shortage exists or has ended.

Rather than the rigid analysis Plaintiffs demand, the statutory text gives FDA discretion in deciding whether a shortage exists. That makes sense. Shortages brought on by different events may involve different factors that impact supply and demand. Suppose a drug's sole manufacturing site is struck by a natural disaster and rendered inoperable. In that event, the extent of damage to the facility and the timeline to bring it back online are highly relevant. But where a drug shortage is caused by the scarcity of an ingredient, FDA's analysis may consider the company's current and future ability to source the *ingredient*. These examples are not purely hypothetical; Congress recognized the variable settings in which a shortage analysis occurs. 21 U.S.C. § 356e(b)(3) (requiring FDA to list the cause of the delay, including shortages of ingredients or discontinuance in manufacture of the drug).

Here, the shortage was caused by "high demand," FDA App. 4, so FDA appropriately focused on whether Lilly's ability to supply tirzepatide had caught up with the demand, FDA App. 16–41. FDA determined at the outset that the focus was on whether "Lilly's supply is currently meeting or exceeding demand" and whether supply "will meet or exceed projected demand." FDA App. 13. Indeed, as the Court found, "[o]n multiple occasions, the Delisting Action clarifies that it considered the previously produced supply and demand numbers for [redacted] to [redacted], as well as the recently released [redacted] numbers and the projected numbers through [redacted]." PI Order 18; *see also id*. ("While the Delisting Action occasionally references narrower time frames, the decision as a whole focuses on a set of data and projected data from a specific time frame—[redacted] to [redacted]."). It is simply inaccurate that FDA did not identify or explain the time period for analysis, much less that the agency outsourced the decision to Lilly. *See* OFA Mot. 9–10.

Presentation of data. Plaintiffs also believe that the data Lilly provided FDA should have complied with certain accounting practices or been easier to audit. OFA Mot. 11–13. But FDA reasonably evaluated the data before it and reasonably explained the conclusions it drew therefrom, which is all the Administrative Procedure Act (APA) requires. *See FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021) ("the [agency] made a reasonable predictive judgment based on the evidence it had"). It nevertheless bears mention that FDA gathered a host of detailed information about the supply and demand for Lilly's drugs, and interrogated Lilly's information through multiple rounds of questions and responses.

While nothing in the drug shortage statute requires a company to provide, or the agency to evaluate, data in any particular form, FDA *did* request that Lilly provide additional information in a particular format, just not in the way Plaintiffs might have preferred. For example, FDA considered the way in which aggregated information regarding total Zepbound/Mounjaro doses might not reflect the supply/demand situation for individual dose strengths, and therefore asked for various data points to be disaggregated (broken down) by individual strength. FDA Opp. App. 1, FDA App. 106, App. 102; *see* FDA App. 17–22 (providing and discussing that information). In other instances, FDA sought more detailed data regarding projected cumulative supply and demand (App. 81), Lilly's inventory (App. 100–103), and wholesalers' inventories (App. 84, FDA App. 171–79). Thus, the record refutes OFA's accusations that FDA "blindly" relied on whatever information Lilly chose to provide. OFA Mot. 18.

Plaintiffs fault FDA for not articulating "which of the competing showings of supply and demand it considered determinative." OFA Mot. 13. But FDA's decision was based on its review of a variety of information, including finished and semi-finished product stock reports, past and current cumulative supply and demand,[2] projected supply and demand, and wholesaler

[2] Plaintiffs ask "what cumulative figures actually show." OFA Mot. 14. Their question is answered in the decision memorandum itself. FDA App. 19 (explaining supply and demand figures for the cumulative supply and demand tables). Though Plaintiffs fault those figures for not showing Lilly's "inventory" at any given point of time, OFA Mot. 14, they ignore Table 1 of the decision memorandum, which does just that, FDA App.19.

information. FDA reasonably found that all of those types of information supported the same ultimate conclusion, and regarded no one source as determinative. *See* FDA App. 17–27. FDA also considered a variety of information provided by compounders and other stakeholders related to supply and demand in reaching its determination. FDA App. 28–41. Nonetheless, Plaintiffs demand to know what single figure was dispositive because they say there is an inconsistency between two of the charts in FDA's decision. OFA Mot. 14. Plaintiffs, however, are comparing Table 1 of the decision memorandum (which reports Lilly's net inventory[3] on [redacted], as around [redacted] doses) with Table 4 (which Plaintiffs say reports the *cumulative net* supply/demand as of [redacted] as [redacted] doses). *Id.* It is not obvious what Plaintiffs are referring to in Table 4, which does not reflect any apparent [redacted] figure for [redacted], but, in any event, figures from Table 1 and Table 4 do not need to match to be accurate: Lilly's net inventory *on hand* at a given point in time (as reflected in Table 1) need not match the *cumulative net* supply/demand at the time. As Lilly explained, these were different data sets based on different metrics, and were not intended to represent the same thing. FDA App. 186.[4]

Up-to-date. Congress requires the shortage list to be "up-to-date," 21 U.S.C. § 356e(a), which to Plaintiffs means that FDA can *only* consider the most recent information available. OFA Mot. 15. This argument is at odds with both the statutory text and what FDA did. Congress told FDA to maintain "an up-to-date list," but otherwise left to the agency's discretion how to meet that requirement, including any temporal qualifications on evidence. Here, FDA *did* consider the

[3] Plaintiffs claim FDA misinterpreted the "stock report" information it received from Lilly, from which FDA reproduced "net inventory balance information" in Table 1. OFA Mot. 22–23. Table 1 reported "inventory *net* of open orders" and FDA accurately and consistently described that inventory as "excess" because it represented inventory left over after fulfilling all open orders. FDA App. 17–19; *see, e.g.*, FDA App. 209 (one of Lilly's stock reports).

[4] Plaintiffs also fault FDA for overlooking "obvious questions about product storage, loss, and longevity" and say it is not "realistic" for a dose from [redacted] to be counted as part of the "cumulative demand" in [redacted]. OFA Mot. 14. To the extent Plaintiffs suggest that Lilly may have kept the literal same doses from [redacted] on its shelves through [redacted] and that Lilly should not have counted them due to expiration, FDA did not need to ask Lilly to know that any rational manufacturer would ship out its older doses first, not its newest.

most recent information available, and focused on it at multiple points. *See* FDA App. 19 (considering information provided to FDA two days before the decision). *And* FDA permissibly considered older data including information demonstrating [redacted], *see* FDA App. 26 & n.57, and information demonstrating positive trends such as an "increasing amount of additional supply over the course of the year," FDA App. 19. In other shortages, older data might prove relevant for other reasons, such as showing seasonal fluctuations in demand.

Geographic scope. Plaintiffs argue that a "shortage" under the statute could be "regional" and fault FDA for evaluating the evidence for a "national" shortage. OFA Mot. 15–16. FDA is obligated to "maintain an up-to-date list of drugs that are determined . . . to be in shortage *in the United States*." 21 U.S.C. § 356e(a). The statute, moreover, defines a drug shortage as "a period of time when the demand or projected demand for the drug *within the United States* exceeds the supply of the drug." 21 U.S.C. § 356c(h)(2) (emphasis added). Corresponding with that nationwide focus, the restriction on an outsourcing facility compounding drugs that are "essentially a copy of an approved drug" is *entirely* lifted if the product is identical or nearly identical to an approved drug that appears on the drug shortage list, 21 U.S.C. § 353b(a)(5), (d)(2)(A). Similarly, the "essentially a copy" restrictions on 503A compounding are *entirely* lifted if the approved drug is in shortage. *Id*. § 353a(b)(1)(D). These statutory provisions do not contemplate the lifting of compounding restrictions in some geographic areas but not in others, *see id*. §§ 353a(b)(1)(D), 353b(a)(5), and doing so would make no sense given modern supply chains and drug distribution networks.

Plaintiffs observe that the references in 21 U.S.C. § 356c(h)(2) to "within the United States," and in 21 U.S.C. § 356e(a) to "in the United States," could be read to mean any portion of the United States, OFA Mot. 16. This theory is at odds with this statutory scheme. *See* 21 U.S.C. §§ 353a(b)(1)(D), 353b(a)(5). Moreover, Plaintiffs' "regional shortage" theory lacks any limiting principle, such that FDA might declare a drug shortage at the individual pharmacy level. Plaintiffs fail to address these glaring problems, which doom their interpretation. *See Colonial*

Am. Life Ins. Co. v. Comm'r of Internal Revenue, 491 U.S. 244, 257 (1989) (although "the language on which petitioner relies, taken in isolation, could be read to authorize" the interpretation, "when the statutory and regulatory language is parsed more carefully, petitioner's position becomes dubious, and when the language is read against the background of the statutory structure, it becomes untenable"). Put simply, FDA reasonably applied the plain statutory language to assess whether there was a nationwide shortage of tirzepatide.

Demand for compounded products. Plaintiffs say that FDA should have counted demand for compounded tirzepatide when assessing current demand for Lilly's products. Further, Plaintiffs say it was inconsistent for FDA to consider demand for compounded products when evaluating future demand for Lilly's products after compounding would be curtailed. OFA Mot. 17. FDA did exactly what the statute requires. As Federal Defendants explained, ECF No. 125 (FDA Mot.), compounded products are not the same "drug" that FDA declared to be in shortage. This is for good reason: following Plaintiffs' theory to its logical conclusion, if the agency included (as Plaintiffs propose) compounded versions as part of the drug's available supply, the moment that supply of both the compounded product and the approved drug met overall demand, the shortage would be over and compounding would end. FDA Mot. 7. Then the shortage would *immediately* begin anew due to the absence of the supply of compounded products. *Id.* The cycle would continue indefinitely, which is manifestly not what Congress intended. *See Carpenters Dist. Council of New Orleans & Vicinity v. Dillard Dep't Stores, Inc.*, 15 F.3d 1275, 1285 (5th Cir. 1994) ("A well-accepted canon of statutory construction requires the reviewing court to avoid any interpretation that would lead to absurd or unreasonable outcomes.").

By contrast, FDA properly considered how the restrictions on lawful compounding would impact *future* demand for Lilly's product. Presumably, upon the end of the shortage, some number of patients who had received the compounded version would switch to Lilly's product. Here, FDA provided several reasons why it would not anticipate the transition to be "one-for-one." FDA App. 39–39. But nonetheless, FDA took the known volume of compounded products

and assumed that all patients receiving the compounded product would switch to Lilly's product. FDA App. 36–39. Even under that conservative scenario, the agency reasonably found that Lilly's supply would still meet demand. *Id.*

In sum, FDA correctly interpreted the governing statute, considered the relevant information, and adequately explained its decision. Plaintiffs' motion for summary judgment on Counts Two and Five should be denied.

II. FDA's decision was not arbitrary and capricious (Counts Three and Four)

As in their motion for a preliminary injunction, Plaintiffs ask the Court to focus on "data points from shorter periods of time, within the overall time frame, that could lead to a different result." PI Order 22. The Court rightly rejected that argument, *id.*, and Plaintiffs' new variation on that theme is similarly meritless.[5] Compared to Plaintiffs' reliance on anecdotal information, the Court found that FDA reasonably "g[ave] more weight to specific, reliable, comprehensive, and current information from Lilly." PI Order 26. For the same reasons, Plaintiffs are not now entitled to summary judgment on Counts Three or Four.

Lilly's data. Plaintiffs' first misstep is doing "[redacted]" that completely ignores Lilly's [redacted] data, even though Plaintiffs' own table ("Table C") shows that Lilly's cumulative supply exceeded demand by [redacted] *doses* by [redacted]. *See* OFA Mot. 19 (listing the "total difference" between supply and demand for [redacted]

[5] Federal Defendants recently identified a transcription error in the decision memorandum. One row of Table 6, for the "Total" projected cumulative supply of tirzepatide single-dose pens, incorrectly retained numbers that reflected an earlier projection Lilly had provided. *See* FDA App. 27 (decision), 191 (earlier numbers), 208 (updated numbers). The rest of the Table was and remains accurate, including the "Total Net" values, and the error was not material to FDA's ultimate decision. *See* FDA App. 26–27. The corrected figures appear below in context with the incorrect values crossed out:

Total	[redacted]	[redacted]	[redacted]	[redacted]
Cum. demand	[redacted]	[redacted]	[redacted]	[redacted]
Cum. supply	[redacted]	[redacted]	[redacted]	[redacted]
Net (cum. s–d)	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]; yielding a sum of [redacted]); *see also* FDA App. 22 (Table 4). Plaintiffs say that FDA's consideration of "projected" supply and demand should have ignored Lilly's significant surplus of tirzepatide at [redacted] because it was inconsistent with the statute's directive to keep the list "up-to-date." OFA Mot. 19–20. That blinks reality and common sense. The agency reasonably considered Lilly's existing surplus of tirzepatide because Lilly could use that supply to meet future demand.

Next, Plaintiffs fault FDA for considering Lilly's stated manufacturing capacity of [redacted] per month. FDA explained in its decision memorandum and previously here that it found that assertion to be "credibl[e]." FDA App. 25–27, 39. Plaintiffs disagree, saying it is "obvious[ly]" inconsistent with Lilly's reports showing production of fewer than [redacted] per month. OFA Mot. 20–21. But the fact that Lilly may not have produced [redacted] in the previous months does not mean that it lacked the capacity to do so, then or going forward. Nor would Lilly need to maximize its manufacturing capabilities when its supply [redacted] already outpaced demand. It is nevertheless worth noting that, when the corrected values of Table 4 are accounted for, *see supra* p. 8 n.5, Lilly's updated projection was that it would supply [redacted] more doses in [redacted]. FDA App. 22 (cumulative supply of [redacted] in [redacted]), 27, 208 (showing projected cumulative individual strength supply, when added showing total supply of [redacted] in [redacted]).

Slicing and dicing Lilly's data, Plaintiffs claim that in [redacted], there was "literally a period of time where supply fell below demand." OFA Mot. 21–22. For Plaintiffs to arrive at a claimed [redacted] discrepancy, Plaintiffs' analysis starts by ignoring the data's limitations, extrapolates from a table intended for a different use, and ultimately compares apples (orders received) to oranges (doses shipped). They have not identified a period of shortage.

Plaintiffs start at Table 5 (FDA App. 24), which reported the volume of "units" (each of which had four doses) that Lilly supplied to wholesalers during [redacted]. OFA Mot. 22. The "[redacted]" table was provided to FDA on [redacted], *see* FDA App.

168, 172, but Plaintiffs assume that it reflects only [redacted] and use those values to extrapolate a number [redacted]—shipped to wholesalers in [redacted], OFA Mot. 22. Plaintiffs then look to the table showing Lilly's cumulative demand, Table 4, and glean what they say was the monthly "demand" for [redacted]: [redacted]. OFA Mot. 22. Plaintiffs then subtract [redacted] from [redacted] to declare a "shortage" of [redacted], *id.*—about [redacted].

Plaintiffs themselves describe their analysis as "a limited comparison," OFA Mot. 21 but, even assuming their methodology is valid, Lilly explained when reporting the "demand" values that those numbers refer to "actual orders *received* from wholesalers." FDA App. 145. Plaintiffs' comparison is therefore between doses "shipped" and "orders received," values that should not be expected to exactly align for any given month. Some percentage of orders during that period could easily have been received [redacted] but not shipped until [redacted] so Plaintiffs' "limited comparison" sheds no light on Lilly's ability to fulfill its orders.

A "shortage" based on that data would also be inconsistent with other information before FDA because, [redacted], Lilly reported a net inventory of [redacted]. FDA App. 19. And Plaintiffs completely overlook an important element of Lilly's data that casts a long shadow over all their arguments. Lilly's data consistently showed [redacted] of semi-finished doses of tirzepatide on hand, which gave it the "ability" to supply finished products "relatively quickly." FDA App. 18–19. Plaintiffs do not address this stockpile. So to satisfy any unexpected increase in demand, Lilly indisputably had a robust inventory of semi-finished product that it could quickly convert to finished product.

Other Evidence. Contrary to Plaintiffs' claims, OFA Mot. 23–27, FDA reasonably evaluated the other evidence before it. Plaintiffs first point to "screenshots of wholesalers' webpages" as demonstrating a national shortage of tirzepatide and erroneously argue that FDA ignored this evidence. In fact, FDA specifically asked Lilly to explain the distribution channels for its products, and Lilly gave explanations for why some screenshots showed limited supply. App. 81–82 (Oct. 28, 2024 question), 84–94 (Nov. 5, 2024 response), 100–103 (Nov. 26, 2024

follow-up); 104–122 (Dec. 6, 2024 response). Among other things, Lilly explained that [redacted]. App. 112. [redacted] App. 112–13. [redacted] App. 113. [redacted] App. 113. Rather than disregarding the screenshots in the record, FDA carefully evaluated them and correctly found that they were of limited probative value. FDA App. 31–33; *see Prometheus Radio Project*, 592 U.S. at 426 ("The FCC did not ignore the Free Press studies. The FCC simply interpreted them differently.").

Plaintiffs cannot show otherwise. Plaintiffs contest FDA's observation that the screenshots had "limitations" by citing some that had date information [redacted]. OFA Mot. 24 (citing App. 218–34, App. 387–88, App. 395–97, App. 402–403). But many of the screenshots concern a drug not at issue in this case (*see* App. 221–22, 224–25, 233–34), and others do not involve wholesalers' websites at all (*see* App. 402–403). More importantly, the screenshots are consistent with Lilly's explanations to FDA, because [redacted] *See* FDA App. 177; *see also* FDA App. 33.

Plaintiffs also claim that screenshots of [redacted] website containing statements like [redacted] demonstrate that pharmacies were unable to order tirzepatide from that wholesaler. OFA Mot. 24 (citing App. 576–78, 589, 623,

667–69, 679–80, 682, 714). But FDA acknowledged these screenshots, too, and discussed their limitations. FDA App. 32; *see also* FDA App. 177–78 ([redacted]), 199–200 ([redacted]). Moreover, all the screenshots are listed as [redacted] so they represent only a snapshot of that time. *See, e.g.*, App. 576.

Next, Plaintiffs question FDA's assessment of survey data, contending that one survey encompassed shortage reports from "tens of thousands" of individuals. OFA Mot. 24–25 (citing App. 362–65). Plaintiffs refer to the "hims & hers" survey, which included 27,969 responses regarding tirzepatide between September 1 and November 9, 2024. App. 362–65. As FDA found, individual reports are better explained by localized supply chain issues, not a national shortage. App. 34. Moreover, neither the hims & hers survey nor the other one cited by OFA, *see* App. 249–50, were reliable or detailed. Plaintiffs protest that the survey data was "as detailed as descriptions get" because they included a variety of zip codes and asked whether the respondent had attempted to fill their prescription at more than one pharmacy. OFA Mot. 25 (citing App. 249–50). But as FDA pointed out, it was "not clear how this information was collected" and did not "include details of the reported individual experiences," such as whether the respondent was reporting an "inability to get a prescription from a doctor" or to "get insurance coverage," neither of which would be relevant to supply or demand. App. 34. FDA also observed that using internet forms to collect data "significantly limit[ed]" the surveys' "probative value" because the respondents were not necessarily representative of the patient population, and because some individuals may have submitted multiple responses. App. 35. FDA permissibly found that this survey failed to "undermine or outweigh the information submitted by Lilly." App. 32.

The anecdotal news reports that FDA received also had limited probative value, consisting of "personal accounts of inability to get a particular product at a particular time." App. 37. Plaintiffs argue FDA "addressed none of it on the merits" and "ignored" reporting that was "unfavorable to its conclusions." OFA Mot. 25–26. This is incorrect. This Court previously found

that FDA specifically addressed the news reports and that it was "not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly, than news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA." PI Order 26.

Plaintiffs also incorrectly assert that FDA "zero[ed] out" the volume of compounded product sales and "disregard[ed] demand for compounded products." OFA Mot. 26. FDA specifically acknowledged the volume of compounded tirzepatide and assumed for the sake of analysis that all known demand for compounded products would switch to Lilly's products. App. 38–39. "After a lengthy discussion," this Court correctly determined, FDA reasonably found that "Lilly would be able to meet the projected demand" after compounded drugs were curtailed. PI Order 27–28.

FDA's decision was not arbitrary or capricious, and Plaintiffs' motion for summary judgment on Counts Three and Four should be denied.

III. FDA's decision was an adjudication and not subject to notice-and-comment requirements or publication in the Federal Register (Counts One and Six)

The Court should deny Plaintiffs' motion for summary judgment on Counts One and Six because FDA properly proceeded via adjudication. Plaintiffs recycle (mostly verbatim) arguments from their preliminary-injunction motion that this Court already rejected. *See* PI Order 6–16. It should reject them again. *See* FDA MSJ 12–16.

Plaintiffs resuscitate their claim that FDA's determination was a legislative rule subject to notice-and-comment requirements because it "create[d] law" by "prohibiting" conduct. OFA Mot. 28. But as the Court rightly pointed out, the source of the prohibition was "an existing statute," not FDA's decision. PI Order 16. FDA "simply looked at the evidence presented" to make a "factual determination on whether one number was bigger than another." PI Order 16. The decision did not "promulgate a new policy-type rule or standard," and had "immediate legal consequences for specific parties," both hallmarks of an adjudication, not a rule. PI Order 15.

Plaintiffs posit the decision has "all the hallmarks" of a rulemaking because it "affects the rights of thousands" of entities, affected parties were not "party" to it, and it had "prospective" effects. OFA Mot. 28–30. But "an adjudication can affect a large group of individuals without becoming a rulemaking." PI Order 12 (quoting *Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999)). Indeed, as the Court observed, FDA "routinely" conducts adjudications that affect large numbers of third parties when it evaluates new drug applications. PI Order 13.[6]

Plaintiffs also renew their misguided argument that the shortage determination improperly created and applied a "new methodology." OFA Mot. 33. As set out above, however, FDA did *not* "disregard[] all demand satisfied by compounded supply, dismiss[] all evidence of unavailability, and accept[] the manufacturer's representations without verification or cross-checking." OFA Mot. 33. And even if it had, the Supreme Court recently reaffirmed that "agencies are generally free to develop standards 'either by general [legislative] rule or by individual order' in an adjudication." *FDA v. Wages and White Lion Invs., LLC*, 145 S. Ct. 898, 2025 WL 978101, at *12 (2025) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 202–203 (1947)).

Even if a shortage determination were considered a "rule," the APA's notice-and-comment requirements would not have applied. That is because the drug shortage statute's provisions displace the APA's default notice-and-comment requirements by "necessary implication." *Dorsey v. United States*, 567 U.S. 260, 274 (2012); *see* FDA PI Opp. 18–19. As this Court concluded, FDA could not keep the drug shortage list "up-to-date" if modifying it required notice and comment. "Given the constant fluctuation in national supply and demand numbers for a given drug," the Court rightly observed, "a rule based on data that is more than a month old cannot be said to be based on 'the latest information' available." PI Order 9–10. Further, the statute requires FDA to maintain as confidential the factual material most critical to its decision, and maintaining that confidentiality while also providing the public a meaningful opportunity to comment would

[6] As one example, FDA approval of a drug results in some manufacturers (including Lilly here) receiving a five-year period of exclusivity blocking certain applications of other manufacturers for drugs using the same active moiety. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

be an "unattainable" goal. PI Order 9 n.3. In this context, those provisions are irreconcilable with notice-and-comment requirements, displacing them by necessary implication.

Finally, because FDA's decision was not a legislative rule, it necessarily follows that Plaintiffs are also incorrect when they claim that the decision needed to be published in the Federal Register under 5 U.S.C. § 552(a)(1)(D). Am. Compl. ¶¶ 103–107 (Count Six); OFA Mot. 33. The Court should therefore also deny Plaintiffs' motion for summary judgment on Count Six.

CONCLUSION

Plaintiffs' motion for summary judgment should be denied.

April 16, 2025

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CERTIFICATE OF SERVICE

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April 16, 2025

/s/ *Oliver McDonald*
OLIVER MCDONALD